EUROPEAN PATENT APPLICATION

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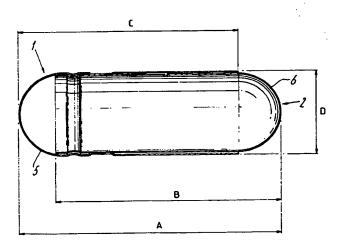
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- 54 Two-part capsule.
- There is described a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5–3.5 to 1.



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MEDICINAL FORMS

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This invention relates to a two part capsule suitable for containing medicaments.

Two part capsules made of gelatin, or of some other similarly rigid film-forming material readily soluble in the body, are conventionally composed of a cylindrical open ended body portion closed by a cap which telescopes over the open end In the conventional capsule, the cap is approxof the body. imately half as long as the body so that part of the latter's length is left exposed and the two parts, body and cap, can be drawn apart. Locking facilities, in the form of mutually engaging grooves or recesses in the cap and body are generally provided to avoid easy or accidental separation of the two These facilities, however, are frequently insufficient parts. to prevent deliberate manual separation, and cases have been reported of such separation for the purpose of illicit tampering with the capsule contents. An object of the present invention is to provide a two part capsule, the construction of which renders such manual separation impossible or more difficult.

Thus, the invention provides a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the

body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.

By assembling the two parts of the capsule so that 5 only the closed rounded end of the body is exposed, insufficient cylindrical surface of the body is presented to enable the purchase necessary for manual separation of the two parts and by the suitable choice of the dimensions of cap and body, a tamper-resisting capsule is therefore obtained which, moreover, 10 retains the overall shape of conventional capsules that have gained acceptance from patients over a considerable period of time. The dimensions may also be such that machinery required in manufacture and filling need only be adapted to produce or handle the longer cap, since the body portion can be of standard 15 dimensions. Such production machinery can be of the usual kind in this art, with pins which are dipped into fluid gelatin, methyl cellulose, cellulose acetate or other suitable film material, the walls of the cap and body preferably being of equal thickness throughout.

20 The closed ends of the cap and body are preferably hemispherical but other suitable, generally rounded, shapes can also be employed. Thus, only the hemispherical portion of the body protrudes from the cap, so that no portion of the cylindrical part of the body is exposed to provide a grip by which the two parts of the capsule can be drawn apart.

The cap and body are preferably of the same length so that the open end of the body portion abuts against the closed end of the cap. Other dimensions are possible, however,

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provided that they allow the body to fit within the cap with only its end protruding. The ratio of the length to diameter of cap is preferably in the range of 2.1-2.6 to 1, for example from 2.3-2.45 to 1 and that of the body preferably in the range of 2.2-2.7 to 1, for example from 2.4-2.6 to 1. It should be noted that when dimensions of capsule, cap and body are mentioned it is the external dimensions that are intended.

We have found that the ratio of cap length to the overall length of the capsule is preferably from 0.8-0.9 to 1, such as from 0.82 or 0.85-0.9 to 1.

The invention is illustrated by way of example with reference to the accompanying Drawings, in which:

Figure 1 is a partial sectional view of one embodiment of a two part capsule according to the invention;

Figure 2 is a view of the cap of the capsule illustrated in Figure 1; and

Figure 3 is a similar view of the body of the capsule illustrated in Figure 1.

The capsule comprises a cap (1) and body (2) both comprising a cylindrical portion (3 and 4 respectively) and a closed end portion (5 and 6 respectively) which is of hemispherical shape.

The cap is seen more clearly in Figure 2 and is of the type that includes a shallow annular shoulder (7) and annular groove (8) towards its closed end (5). The cap can be tapered from its open end. The body (Figure 3) bears a corresponding annular groove (9) towards its open end (10), which is positioned so that when the capsule is assembled in

its final locked position and the two annular grooves (4 and 9) are engaged as seen in Figure 1, only the hemispherical closed end of the body (6) protrudes.

The shallow annular shoulder (7) allows the cap and 5 body to be loosely fitted together for storage or transport before the filling operation takes place and is positioned such that sufficient of the surface of the cylindrical portion is exposed to permit disengagement from the cap in preparation for the filling operation. Thus when assembling the cap and body 10 for transport before the filling operation, the open end of the body is slid within the cap as far as the annular shoulder (7) against which the open end (10) of the body lightly abuts and is held from further engagement. After disengagement and the filling operation, the cap and body can be engaged once more and the body slid past the annular shoulder (7) so that the 15 grooves (8 and 9) lock together.

With regard to the dimensions of the capsule, the overall external length (A) (Figure 1) of the assembled capsule and the external diameter of the cap (D) are in the ratio of 2.5 to 3.5 to 1 preferably in the range of 2.7 to 3.0, to 1. The length (B) of the body and the length (C) of the cap are substantially equal and the diameter of the body is such as to provide sliding engagement within the cap.

Examples of the dimensions of capsules according to the invention are as follows:

	Size	* Capsule	Body		Cap		Volume	
		mm	ı	nm.	mm		cc	
		length	length	diameter	length	diameter**		
5		(A)	(B)		(C)			
	0	21.8	18.6	7.33	18.6	7.63	0.67	
	1	19.5	16.5	6.62	16.5	6.90	0.48	
	2	17.8	15.1	6.07	15.1	6.35	0.37	
10	3	15.9	13.5	5.56	13.5	5.82	0.27	
	4	14.5	12.3	5.06	12.3	5.32	0.20	
	*	internationa	1 size					

^{**} does not take into account taper

15 It will be appreciated that the invention has been described in relation to a preferred type of capsule, and many variations are possible. For example, the capsule cap and body need not posses the particular combination of grooves and shoulder as shown in the Drawings. Moreover, the length of the cap need not be equal to that of the body provided it is long enough to provide sufficient cover for the body.

A preferred capsule of the invention is one in which the cap has an annular groove towards its closed end and the body has a corresponding annular groove near its open end, the grooves being so positioned that in the assembled capsule they lock together and only the closed end of the body protrudes from the cap.

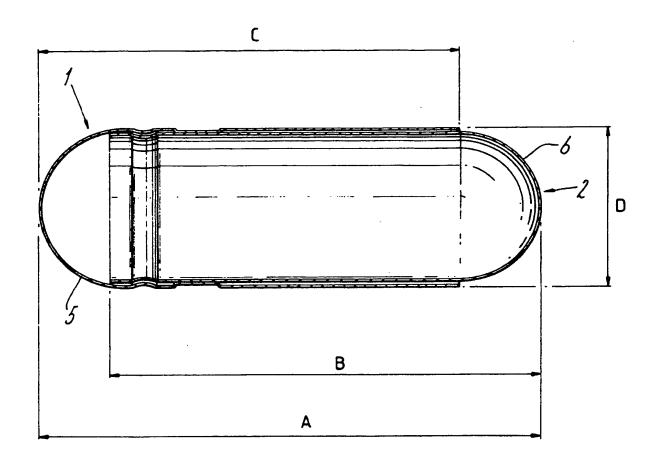
CLAIMS

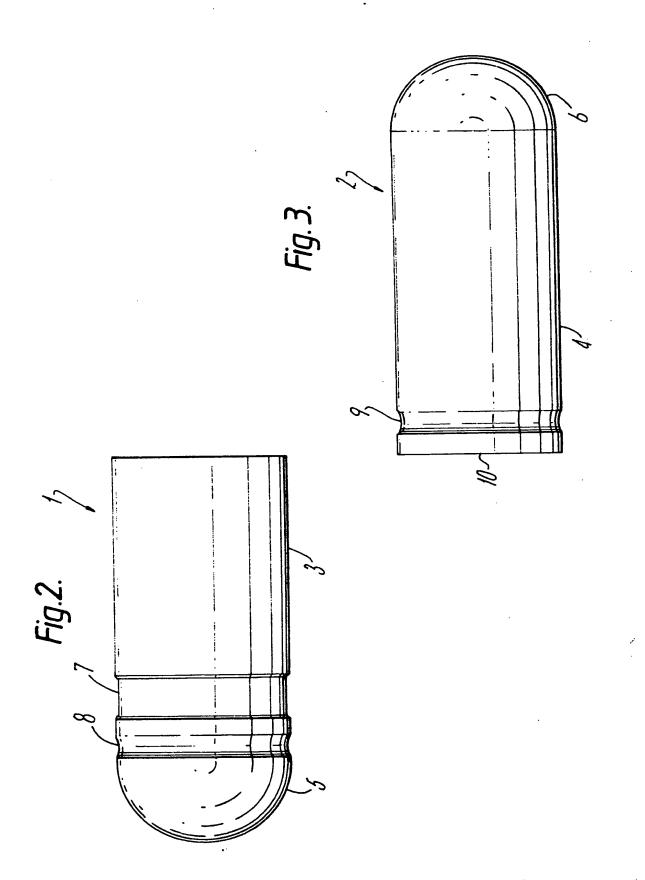
- 1. A two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule

 5 comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the body protrudes externally from the

 10 cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.
 - 2. A capsule according to claim 1 in which the closed ends of the cap and body are hemispherical.
- 3. A capsule according to either of claims 1 and 2 in
 15 which the ratio of cap length to capsule length is from
 0.8-0.9 to 1.

Fig.1.





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EUROPEAN SEARCH REPORT

0 1 4 3 5 2 4 . Application number

EP 84 30 6430

		SIDERED TO BE RELEVA	NT	
Category	Citation of document w of rele	vith indication, where appropriate, evant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CI.4)
Y	FR-A-1 461 033 CORP.) * Figure 1; cla		1	A 61 J 3/07
A	·		2	
Y	CO.)	(ELI LILLY AND nes 53-62; figures	1	
A	FR-A-1 153 998 CORP.) * Figure 3 *	(R.P. SCHERER	1,2	
P,A	EP-A-0 110 500 CO.) * Figures 1,2;	 (WARNER-LAMBERT claims 1, 2 *	1,2	TECHNICAL FIELDS SEARCHED (Int. CI.4) A 61 J 3/07
	The present search report has b	een drawn up for all claims		
	Place of search BERLIN	Date of completion of the search 14-12-1984	BARNY	Examiner DE ROMANET P.M
Y : part doc A : tech O : non	CATEGORY OF CITED DOCL icularly relevant if taken alone icularly relevant if combined wument of the same category inological background-written disclosure rmediate document	E: earlier pat after the fi ith another D: document L: document	ent document, b ling date cited in the app cited for other r f the same pater	ring the invention out published on, or lication easons at family, corresponding